DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE CENTERS FOR DISEASE CONTROL

MINUTES OF MEETING

Immunization Practices Advisory Committee October 18-19, 1983 Atlanta, Georgia

The Immunization Practices Advisory Committee (ACIP) met in Conference Room 207 at the Centers for Disease Control in Atlanta, Georgia, on October 18-19, 1983. Those in attendance are listed below:

COMMITTEE MEMBERS PRESENT

- Dr. James Chin, Chairman
- Dr. Ellen S. Alkon
- Dr. Anne A. Gershon
- Dr. Samuel L. Katz
- Dr. Joan K. Leavitt
- Dr. Edward A. Mortimer
- Dr. Frederick L. Ruben
- Dr. William Schaffner
- Dr. Stephen C. Schoenbaum

Liaison Representatives

- Dr. Philip A. Brunell (AAP)
- Dr. J. Michael Dixon (NACI)
- Dr. Theodore C. Eickhoff(AMA)
- Dr. Richard J. Jones (ACP)

Executive Secretary

Dr. Jeffrey P. Koplan

COMMITTEE MEMBERS ABSENT

Dr. D. A. Henderson

Ex Officio Members

Dr. William S. Jordan, Jr. (NIH)

(represented by Dr. George Galasso)

Dr. Harry Meyer, Jr., (FDA)

(represented by Dr. J. Petricciani)

Liaison Representatives

Dr. Peter A. Flynn, Capt., USN (DOD)

INVITED PARTICIPANT

Dr. Gregory Istre

HHS STAFF PRESENT

BUREAU OF BIOLOGICS, FDA

Dr. John C. Petricciani

Dr. Carolyn Hardigree

NATIONAL INSTITUTE OF ALLERGY AND

INFECTIOUS DISEASES, NIH

Dr. George Galasso

CENTERS FOR DISEASE CONTROL

Office of the Director

Dr. William Foege

Dr. Gary Noble

Mr. Gene Matthews

Ms. Verla Neslund

Ms. Karen Kaunitz

Center for Infectious Diseases

Dr. Claire Broome

Dr. Stephen Cochi

Dr. Roger Feldman

Dr. Alan Kendal

Dr. Thomas Monath

Ms. Julia Garner

Dr. Stephen Hadler

Dr. Gary Schatz

Dr. Frederic Shaw

Center for Preventive Services

Dr. J. Michael Lane

Dr. Alan Hinman

Dr. Kenneth Bart

Center for Preventive Services (continued)

International Health Program
Office

Dr. Myron G. Schultz

Dr. Roger Bernier

Dr. Walter Orenstein

Dr. Edward Brink

Dr. Alan Bloch

Dr. Benjamin Nkowane

Dr. Ida Onorato

Dr. Stephen Preblud

Dr. Harrison Stetler

John C. Hoffman

Victor A. Jegede

Joseph Kuo

L. William McIntosh

B. A. Ruben

Karlyn L. Shedlowski

Mason G. Stout

Dr. Ronald J. Vallancourt

Dr. Ralph A. Vosdingh

Charles S. Taylor

OTHERS PRESENT

Gerald Schiffman

Dr. Lance K. Gordon

Douglas B. Reynolds

Mary B. Ritchey

LCDR David E. Conwill, MC, USN

Dr. H. Bruce Dull

Raymond W. Tiedemann

Mark Levner

Dr. Harry Guess

Dr. Eva Lydick

The meeting was opened at 8 a.m., October 18, 1983, by the Chairman, Dr. James Chin, who welcomed the Committee and introduced three new Committee members, Drs. Ellen Alkon, Anne Gershon, and Theodore Mortimer. Dr Chin emphasized the fullness of the agenda and the consequent need for adhering to the recommended timetable.

ADULT IMMUNIZATION

Dr. Alan Hinman of the Division of Immunization opened a discussion of the draft statement on Adult Immunization which had been received and reviewed by the Committee members for their perusal prior to the meeting. The Adult Immunization statement, a supplement to the ACIP General Recommendations on Immunizations statement (MMWR Vol. 32, 1983), is an overview of the immunizations for adults and is to be used in conjunction with the detailed statements for each vaccine. The statement focuses on (1) vaccine preventable diseases and vaccine indications, and vaccine specific side effects, adverse reactions, precautions and contraindications for vaccines recommended for adults; (2) immunization recommendations for all adults and for special occupations, lifestyles, travel, environmental situations and health status groups. The Committee discussed and agreed that a statement should be included for sewage workers who may be at increased risk. Dr. Mortimer suggested that the paragraph on "Patient Information" in the "General Recommendations on Immunization" statement be repeated in the Adult Immunization statement and that perhaps one statement should always accompany the other.

The Committee continued discussion of the Adult Immunization statement at 8 a.m. on October 19. The Committee decided that the statement would be revised to include suggestions recommended by the Committee and that every effort would be made to make the text correspond to existing individual ACIP statements. The statement would again be circulated through correspondence to the Committee for review and approval prior to publication as a supplement in the MMWR early next year. Each Committee member was to review the statement and send their comments to Dr. Koplan within 10 days.

INACTIVATED POLIO VACCINE

Dr. Roger Bernier of the Division of Immunization presented an update on improved inactivated polio vaccine (IPV) and the cost of IPV. He gave data on human studies in progress in the United States and foreign countries using IPV-Merieux, IPV-Connaught, and OPV-Lederle. Preliminary results of a limited number of children receiving either OPV or Merieux-IPV show that the percent of children with detectable antibody is high and equivalent in both groups at all ages tested.

MEASLES AND RUBELLA

Dr. Hinman reviewed the current status of the diseases. There was an outbreak of measles at Indiana University this year. There has been a decrease in rubella cases. Elimination of measles and rubella may be possible in the next few years.

PERTUSSIS

Dr. Hinman and his staff presented data from studies on pertussis vaccination of infants and children with previous personal history of febrile, idiopathic, and secondary convulsions. The influence of prior personal and family history of seizures on the incidence of neurologic disorders following vaccination in the United Kingdom and worldwide was discussed.

The Committee discussed the definition of seizures and neurologic disorders, ascertainment of family history by the physician, and vaccine contraindications.

Discussions were held on whether to immunize a child with a history of convulsive disorders as protection against pertussis, and whether a child with convulsive tendencies is any more likely to develop cerebral complications from pertussis immunizations than any other child. Does a history of convulsions or an active convulsive disorder necessarily contraindicate the administration of pertussis inoculations in view of the frequency and severity of complications of whooping cough in children, particularly in the very young child?

The three manufacturers of pertussis vaccines are working on developing a new vaccine, but this is several years away.

VARICELLA-ZOSTER IMMUNE GLOBULIN

Dr. Hinman and his staff distributed to the Committee a revision of the statement on Varicella-Zoster Immune Globulin (VZIG) for the Prevention of Chickenpox which had been sent previously to the Committee members for their review and comments. This initial statement by the Committee covers the use of VZIG for immunocompromised individuals of any age, normal adults, pregnant women, and premature infants.

Discussions followed regarding changes in the revision in the draft. With the increase in the supply of VZIG, some restrictions can be lifted; however, the supply of VZIG is still limited and is recommended primarily for immunocompromised children and certain newborn infants exposed in utero. A Merck marketing representative stated that vaccine may possibly be available

to immunocompromised children free of charge. Dr. Gershon stated that she has immunized 35 adults without incidence.

It was the consensus of the Committee that an accelerated effort is needed to make this vaccine available to susceptible persons in identified high-risk groups. Dr. Chin will write a letter to Merck, Sharp & Dohme to encourage them to take steps required to obtain permission from the Office of Biologics to begin distribution of this vaccine to persons at high risk of complications to varicella.

Each Committee member was asked to review the statement and send their comments to Dr. Koplan within 10 days.

YELLOW FEVER

Dr. Monath gave the results of a study on the effect of cholera vaccine on yellow fever antibody responses following 17D vaccine. The conclusion of the study reveals that although there are weaknesses and flaws in all available studies, evidence that cholera vaccine impairs yellow fever vaccine immunity warrants a recommendation in the yellow fever vaccine statement.

A revised yellow fever vaccine statement will be finalized before the next ACIP meeting.

JAPANESE B ENCEPHALITIS

Dr. Monath reported that on May 17, 1983, the Division of Vector-Borne Diseases received approval from BOB/FDA to proceed with a preliminary evaluation of the BIKEN Japanese Encephalitis vaccine as an investigational new drug (IND). Following an approved protocol, investigators administered the vaccine to persons traveling to Asia. Three lots of BIKEN vaccine were used. All lots had passed BIKEN standards for purity and potency.

HEPATITIS B IMMUNE GLOBULIN (HBIG)

Drs. Stephen Hadler and Gary Schatz gave results of studies on incidence of hepatitis B infection in contacts of patients with acute hepatitis B. This included heterosexual partners, other household contacts, household children, and adults. There is no evidence of AIDS appearing in a person who received HBIG, via the CDC/AIDS surveillance system.

The Committee discussed the definition of acute sexual contacts, guidelines for handling household contacts for carrier, and whether all members of household should be immunized. The Committee requested that a statement be prepared by the Hepatitis Division making recommendations on HBIG and IG use in sexual and household contacts.

HEPATITIS B VACCINE

Dr. Shaw reported on a survey made by Merck, Sharp & Dohme as of August 15, 1983.

There is no data suggesting a causal relationship between AIDS and hepatitis B vaccine.

PNEUMOCOCCAL VACCINE

In 1981 when the ACIP recommendations on Pneumococcal Polysaccharide Vaccine were published in the MMWR, the vaccine contained 14 types. As of July 1983 the number of types in the vaccine increased to 23.

INFLUENZA VACCINE, ANTIVIRALS, AND SURVEILLANCE

Dr. Alan Kendal presented preliminary results of studies on the hemagglutination inhibition of influenza A (HlN1) viruses; preliminary analyses of frequency and distribution of new influenza A (HlN1) variants received at the WHO Collaborating Center for Influenza, CDC, Atlanta; hemagglutination inhibition antibody response to 1983 HlN1 variants in persons vaccinated with A/Brazil/11/78.

Dr. Kendal will work with Drs. Schoenbaum and Ruben to prepare a draft on antivirals. If possible, this will be prepared and circulated to the Committee members for their comments prior to the February 1984 meeting.

HAEMOPHILUS INFLUENZAE

As a followup to the discussion on <u>H. influenzae</u> type b (HIB) disease and the specific issues regarding vaccine prevention using the existing polysaccharide (PRP) vaccine at the Spring 1983 meeting, Drs. Claire Broome and Stephen Cochi provided written background materials, which had been received and reviewed by the Committee members prior to the meeting, that elaborated on that presentation and focused on the cost-benefit of possible community-wide vaccination of children in the United States at 18 months of age.

There is no licensed HIB polysaccharide vaccine product available at this time. For this reason, a formal draft recommendation has not been prepared on H. influenzae. This information was presented to the Committee as an aid in determining whether a consensus statement on the usefulness of such a vaccine should be issued.

Dr. John Petricciani from the National Center for Drugs and Biologics, FDA, and Dr. George Galasso from NIAID, NIH, gave the status of HIB vaccines and general requirements for licensure.

Dr. Leavitt asked how many States have <u>H. influenzae</u> as a reportable disease; Dr. Broome replied that she thinks 27 States do.

OTHER ACIP BUSINESS

Dr. H. Bruce Dull complemented Dr. Hinman on the text of the Adult Immunization statement, the effort put into it, and the sentence structure. The Committee discussed whether to index the text since it is a very long document. The first 17 pages deal with approach to adults only.

The FDA Panel meeting will be in January 1984. Immunization Conference is in Boston on May 21, 1984.

Dr. Chin recognized Dr. Foege and thanked him for his support to the ACIP during his tenure as Director of CDC.

FUTURE ACIP MEETING DATES

The next ACIP meeting was planned for Tuesday and Wednesday, February 7-8, 1984, at which time topics for discussion will include: revised guidelines for rubella vaccination, oral versus inactivated polio vaccines, recommendations for 1984 influenza vaccine use, update on hepatitis B vaccine use, and update on pneumococcal vaccine use.

ADJOURNMENT

With the thanks of the Chairman, the meeting was adjourned at 3 p.m.

I hereby certify that, to the best of my knowledge, the foregoing summary of minutes is accurate and complete.

James Chin. M.D.

Date